

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

October 26, 2007 (October 22, 2007)
Date of Report (Date of earliest event reported)

DEL CATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-16133
(Commission File No.)

06-1245881
(IRS Employer
Identification No.)

600 Fifth Avenue, 23rd Floor
New York, NY 10020

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(212) 489-2100**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 8.01 OTHER EVENTS.

On October 22, 2007, Delcath Systems, Inc. (the "Company") received a letter from the U.S. Food and Drug Administration (the "FDA") recommending that the Company temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal ("GI") safety concerns.

The recommendation was issued by the FDA following reports of four serious adverse GI events that the Company submitted to the FDA, the National Cancer Institute, the Institutional Review Board and the Data Safety Monitoring Board, that may have been related to the infusion of melphalan. The Company plans to submit to the FDA its analysis of these adverse events and their relation to the Delcath System within fifteen days. The Company also intends to meet with the FDA to address the issues it raised, and to present changes that have already been made to the trial protocols that the Company believes will remedy the FDA's safety concerns. Until such time, the Company has decided to voluntarily defer accrual of new patients in the Phase III and Phase II trials pending a meeting with the FDA. The Company anticipates that patients currently enrolled in the trials will continue to receive their treatments under the approved protocols.

The Company's management hosted an investment conference call at 10:00 a.m. Eastern Time on Tuesday, October 23, 2007 to discuss these developments and to answer questions.

A copy of the Company's press release announcing the events described above is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

- (a) Not applicable.
- (b) Not applicable.
- (c) Not applicable.
- (d) Exhibits

No.	Description
99.1	Press release of the Company dated October 23, 2007

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: October 26, 2007

DELCATH SYSTEMS, INC.

By: /s/ Richard L. Taney
Name: Richard L. Taney
Title: Chief Executive Officer

EXHIBIT INDEX

No.	Description
99.1	Press release of the Company dated October 23, 2007



Company Contact:
Delcath Systems, Inc.
Richard Taney
(212) 489-2100
www.delcath.com

Investor Relations Contacts:
Lippert/Heilshorn & Associates, Inc.
Anne Marie Fields
(afiels@lhai.com)
(212) 838-3777
Bruce Voss (bvoss@lhai.com)
(310) 691-7100
www.lhai.com

DEL CATH VOLUNTARILY DEFERS ACCRUAL IN CLINICAL TRIALS

Management to Host Conference Call Today at 10:00 a.m. Eastern Time

NEW YORK (October 23, 2007) – Delcath Systems, Inc. (Nasdaq: DCTH) announced today that it received a letter late yesterday from the U.S. Food and Drug Administration (FDA) recommending that the Company temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the Agency to discuss certain gastrointestinal (GI) safety concerns. The recommendation was issued by the Agency following reports of GI events submitted by the Company to the FDA that may have been related to the infusion of melphalan. Delcath plans to submit to the FDA its analysis of these adverse events and their relation to the Delcath System within the next fifteen days.

Delcath had previously reported four serious adverse events, two of which resulted in deaths, to the FDA and the National Cancer Institute (NCI) Institutional Review Board (IRB) as well as to the Data Safety Monitoring Board (DSMB) for the Phase III trial. Delcath worked with the Principal Investigator to amend the protocols to prevent future adverse events and those changes were approved by the NCI IRB and implemented into the trials.

Delcath plans to meet with the FDA to address the issues raised by the Agency and to present changes that have already been made to the trial protocols that the Company believes will remedy the Agency's safety concerns. In addition, Delcath will present the Agency with current data from the clinical trials that will allow for the analysis of the clinical benefits of the Delcath System. It is hoped that the FDA will agree that the changes that have already been implemented in the protocol will mitigate, and possibly eliminate, the incidence of these GI events. Until then, the Company will voluntarily defer accrual of new patients in the Phase III and Phase II trials. The Company anticipates that patients currently enrolled in the trials will continue to receive their treatments under the approved protocols.

Richard L. Taney, President and Chief Executive Officer of Delcath, commented, "We are prepared to meet with the FDA as soon as possible, and will present a thorough analysis of these GI episodes. We will update our investors promptly on resolution of this issue."

Conference Call

Delcath management will host an investment conference call beginning at 10:00 a.m. Eastern Time today, Tuesday, October 23, 2007 to discuss these developments and to answer questions. To participate, please dial (888) 301-2290 from the U.S. or (706) 679-2025 from outside the U.S.

About Delcath Systems, Inc.

Delcath Systems is the developer of percutaneous perfusion technology for organ- or region-specific delivery of therapeutic and chemotherapeutic agents. The Delcath System is currently being tested with the drug Melphalan in a Phase III trial of patients with metastatic ocular and cutaneous melanoma in the liver, and a Phase II trial of patients with primary liver cancers and metastatic tumors in the liver from neuroendocrine cancers and adenocarcinomas, as well as patients with melanoma who previously received isolated perfusion. The Company's intellectual property portfolio currently consists of 18 patents on a worldwide basis including the U.S., Europe, Asia and Canada. For more information, please visit the Company's website www.delcath.com.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to our ability to successfully complete Phase III clinical trials and secure regulatory approval of our current or future drug-delivery system and uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

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